

Nelson, Bettie L

From: Michael Szwane (402)437-4880 [Michael.Szwane@mdsps.com]
Sent: Thursday, May 02, 2002 4:40 PM
To: Hans-Juergen.Roethig@pmusa.com; bettie.l.nelson@pmusa.com
Cc: Bill Tracewell; Robert Earl; Marie Simerly; Staci McDonald; Kimberly Prchal; Kirk Newland; Paul Johnson; Denise Mainquist; Steve Hambek; William Bumgardner; James Cunningham; Chad Briscoe; Dawn Carpenter
Subject: 28123-Philip Morris Long Term Study
Sensitivity: Confidential



28123_F2_02MAY028123_02MAY02_A
2_Philip Morris... ATTACHMENTS_Phil..

Hans/Bettie,

Attached is the final protocol and Selected Attachments for 28123-Philip Morris Long term study dated May 2, 2002. Both documents were delivered to the IRB secretary this afternoon for inclusion in the IRB packets for the May 7, 2002 IRB committee meeting.

Most changes were administrative resulting from legal review of the protocol at Philip Morris. Summary of major changes:

- 1) Add USA to all reference of Philip Morris throughout
- 2) Consistent use of ACCORD JLI when referring to the lighters or cigarettes. Change name of EHCSS group to ACCORD JLI EHCSS for consistency throughout
- 3) Change reference of cigarette tar content, FTC to cigarette tar delivery, FTC-Method throughout
- 4) Removal of swapping of lighters at visits--Subjects will be re-issued same lighter after downloading of information, cleaning, etc.
- 5) Removal of reference to collection of social economic status/information in Section 5.2
- 6) Clarified information to be captured by the ACCORD JHL lighter during the study for monitoring ACCORD JLI cigarette use
- 7) Include approximate volume of Glucose solution in section 7.10

Thanks,

Michael F. Szwane, Pharm D., MBA
Senior Scientist, Study Design & Protocol Development
MDS Pharma Services - Lincoln, NE
michael.szwane@mdsps.com
(402) 437-4880